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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,680	10/31/2001	Paul L. Feldman	PU3318USw	6805

7590 11/10/2004
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,680

Applicant(s)

FELDMAN ET AL.

Examiner

Brenda Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-14,24,25,28,29,32,34,35,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,28,29,34 and 35 is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9-14,24,25,32,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/26/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1624

DETAILED ACTION

Claims 1, 4, 5, 8-14, 24, 25, 28, 29, 32, 34, 35, 38 and 39 are pending in the application.

This action is in response to applicant's amendment filed August 17, 2004.

Claims 6, 7, 15-17, 19, 20, 26, 30, 31, 36 and 37 have been canceled, claims 1 and 8 have been amended and claims 38 and 39 are newly added.

Response to Amendment

Applicant's amendments filed August 17, 2004 have been fully considered with the following effect:

1. With regards to the objection to the specification under 35 U.S.C. § 132 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the application as filed, disclosed R⁷ substituents include C₁₋₄alkylpyridyl and C₁₋₄alkylimidazolyl at page 3, line 20. However, pyridylmethyl, pyridylethyl, and imidazolylethyl is not specifically disclosed other than in specific species at page 10, lines 20-25, page 11, line 6, Example Ib-5 at page 51, Example Ib-6 at page 51 and Example Ib-8 at page 52. These are species of which R¹, R², R³, R⁴, R⁵, R⁶, W, X, Y, Z, m, n and p are defined as follows:

Example Ib-8 --- R¹ is CH₃, R² is 2-fluorophenyl, R³ is Cl, R⁴ and R⁵ together is a double bond, R⁶ is NHR⁷ where R⁷ is 2-(4-imidazolyl)ethyl, W is H, X is CH₂, Y is CH₂, m is 1, n is 1 and p is 0.

Art Unit: 1624

Example Ib-6 --- R^1 is CH_3 , R^2 is 2-fluorophenyl, R^3 is Cl, R^4 and R^5 together is a double bond, R^6 is NHR^7 where R^7 is 4-pyridylethyl, W is H, X is CH_2 , Y is CH_2 , m is 1, n is 1 and p is 0.

Example Ib-5 --- R^1 is CH_3 , R^2 is 2-fluorophenyl, R^3 is Cl, R^4 and R^5 together is a double bond, R^6 is NHR^7 where R^7 is 4-pyridylmethyl, W is H, X is CH_2 , Y is CH_2 , m is 1, n is 1 and p is 0.

The species where X is NH, Y is O, W is C_1 - C_4 branched alkyl, or straight chained alkyl, Z is O and p is 1, R^2 is phenyl, etc. when R^7 is pyridylmethyl, pyridylethyl, and imidazolylethyl are not positively exemplified or described in the specification.

2. With regards to the 35 U.S.C. § 112, first paragraph rejection of claims 1, 10, 24, 25 and 32 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the application as filed, disclosed R^7 substituents include C_{1-4} alkylpyridyl and C_{1-4} alkylimidazolyl at page 3, line 20. However, pyridylmethyl, pyridylethyl, and imidazolylethyl is not specifically disclosed other than in specific species at page 10, lines 20-25, page 11, line 6, Example Ib-5 at page 51, Example Ib-6 at page 51 and Example Ib-8 at page 52. The species where X is NH, Y is O, W is C_1 - C_4 branched alkyl, or straight chained alkyl, Z is O and p is 1, R^2 is phenyl, etc. when R^7 is pyridylmethyl, pyridylethyl, and imidazolylethyl are not positively exemplified or described in the specification.

Claims 1, 10, 24, 25 and 32 are rejected under 35 U.S.C. 5 1 12, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

Art Unit: 1624

the application was filed, had possession of the claimed invention, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 102, anticipation rejection of claim 1 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that the Bock document is directed to certain urea compounds, i.e. compounds that contain a group -NH-C(=O)-NH- . However, in lines 4-6 of column 18 is a starting material used to prepare the urea containing compounds which teaches the compounds of the instant invention where R^1 is $\text{PHCH}_2\text{-}$, R^2 is phenyl, R^3 is H, R^4 and R^5 together is a double bond, R^6 is NHR^7 where R^7 is 2-propanol, W is H, X is NH, m is 0, n is 1 and p is 0, Registry No. 170228-05-4 and 170227-96-0 are available to view the species.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Bock et al., U.S. Patent No. 5,834,464, for reasons of record and stated above.

4. The applicant's amendments are sufficient to overcome the objection to the specification labeled paragraph 8 in the last office action, which is hereby **withdrawn**.

5. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 101, rejection of claims 6 and 7 labeled paragraph 9 in the last office action, which is hereby **withdrawn**.

Art Unit: 1624

6. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 6 and 7 labeled paragraph 10 in the last office action, which is hereby **withdrawn**.

7. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection of claims 6 and 7 labeled paragraph 11 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated August 17, 2004, the following new grounds of rejection apply:

Information Disclosure Statement

8. The information disclosure statement filed November 26, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Several of the references were not available to the Examiner. It is requested that the applicants submit a copy of the references labeled 6, 7, 18-21 and 24 to complete the record.

Specification

9. The amendment filed August 17, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Art Unit: 1624

- a) (3) R^4 and R^6 form the group $-CR^8=U-V=W$ and
- b) Z is 0 (zero).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specific definition of two species, i.e. the species where n is 2 in claims 38 and 39 are not specifically described in the specification with respect to the genus of Formula (I).

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 1, 4, 5, 9-14, 24, 25, 32, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1, 10-14, 24, 25 and 32 are vague and indefinite in that it is not known what is meant by the two different definitions for the variable p.
- b) Claim 4 is vague and indefinite in that it is not known what is meant by the semi-colon following formula (I).
- c) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety $-\text{CH}_2\text{CH}(\text{CH}_3)$ in the definition of R^1 , which has a carbon atom with only three bonds.
- d) Claim 4 is vague and indefinite in that it is not known what is meant by the definition of R^5 and R^6 together are 0 (zero).
- e) Claim 5 is vague and indefinite in that it is not known what is meant by the moiety 2-chlorophenyl in the definition of R^2 .
- f) Claim 9 is vague and indefinite in that it is not known what is meant by the definition of R^5 and R^6 together are 0 (zero).
- g) Claim 10-14 and 25 recite the limitation " R^8 " in the definition of R^4 and R^8 . There is insufficient antecedent basis for this limitation in the claim.
- h) Claims 38 and 39 do not end with a period indicating the end of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1624

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Yukimasa et al., U.S. Patent No. 5,698,691. Yukimasa teaches the compounds of the instant invention where R^1 is CH_3 , R^2 is 2-chlorophenyl, R^3 is Cl, R^5 and R^6 together is O, R^4 is H, W is H, X is CH_2 , m is 0, n is 1 and p is 0. See examples 11 (Reg no. 165952-78-3) and 15 (Reg no. 165952-82-9).
13. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorsett et al., WO 98/38177. Thorsett teaches the compounds of the instant invention where R^1 is $PhCH_2-$, R^2 is 2-chlorophenyl or 2-fluorophenyl, R^3 is Br or Cl, R^5 and R^6 together is O, R^4 is H or CH_3 , W is H, X is NH, m is 0, n is 1 and p is 0. See examples 8-C Step A, starting material and final product (Reg no. 209985-28-4 and 209985-25-1) and 8-D Step A, starting material and final product (Reg no. 209985-22-8 and 209985-20-6). Relevant pages are herein provided.
14. Claims 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al., U.S. 2002/0055500. Wu teaches the compounds of the instant invention where R^1 is $PhCH_2-$, R^2 is 2-chlorophenyl or 2-fluorophenyl, R^3 is Br or Cl, R^5 and R^6 together is O, R^4 is H or CH_3 , W is H, X is NH, m is 0, n is 1 and p is 0. See examples 8-C Step A, starting material and final product (Reg no. 209985-28-4 and 209985-25-1) and 8-D Step A, starting material and final product (Reg no. 209985-22-8 and 209985-20-6).

Art Unit: 1624

Allowable Subject Matter

15. Claims 8, 28, 29, 34 and 35 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner
Art Unit 1624
November 5, 2004